Remarks

I. Support for the Amendments

Support for the foregoing claim amendments may be found throughout the specification, and in the original claims. Specifically, support can be found, for example, at pages 9-11. No new matter was added by way of these amendments.

II. Status of the Claims

By the foregoing amendments, claims 1, 4, 5 and 8 have been amended, and claims 2, 3 and 13-17 have been canceled. Upon entry of the foregoing amendments claims 1 and 4-12 are pending in the present application.

III. Restriction Requirement

In the Office Action at pages 2-5, the Examiner has required restriction to one of groups I, II and II under 35 U.S.C. § 121. Applicants respectfully traverse this restriction requirement.

Applicants submit that the complete examination of the application would be most expeditiously handled by treating all of the pending claims as a single entity. As Section 803 of the MPEP states, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." It is respectfully submitted that the Examiner has not shown that a search and examination of the entire application would cause a serious burden. No serious burden is created when a simultaneously conducting a

computerized search for the nucleic acids of Group I, the proteins of Group II, and the methods of Group III.

Based on the foregoing, Applicants submit that the restriction requirement is improper and therefore must be withdrawn. However, to facilitate prosecution, as was communicated to the Examiner during a March 9, 2001 telephone conversation, Applicants have provisionally elected, with traverse, Group I (claims 1 and 4-12), and SEQ ID NO: 1.

IV. The Objection to the Specification

In the Office Action at page 5, section 9, the Examiner has objected to the specification because it contains embedded hyperlinks and/or other forms of browser executable code. Applicants have accommodated this objection.

A URL is not considered to be browser executable code if it is not either preceded with *http://* or placed between the symbols "< >." M.P.E.P. § 608.01, page 600-54, Examiner Note. As such, the URLs present in the application, as amended, are not browser executable code, and would therefore not be interpreted by a browser as a link to another web site when the document is placed on the USPTO web site. Reconsideration and withdrawal of this objection are respectfully requested.

V. The Rejection of Claims 1 and 4-12, Under 35 U.S.C. § 101

In the Office Action at pages 6-8, section 10, the Examiner has rejected claims 1 and 4-12 under 35 U.S.C. § 101, for allegedly lacking a patentable utility. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification described multiple utilities for the present invention, including being "useful in the isolation of agronomically important genes...antibody production, gene expression probe, marker, etc." Office Action, at page 6, section 10. Moreover, other utilities are set forth in the specification. *See* page 30 under "Uses of the Agents of the Invention." However, the Examiner contends that none of these utilities constitute a "substantial" or "specific" utility. Applicants respectfully disagree with this assertion.

It is well established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for determining the presence and/or identity of polymorphisms, measuring the levels of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements, screening cDNA genomic libraries, obtaining nucleic acid homologies, detecting and characterizing gene expression, etc. *See* specification at page 30 under "Uses of the Agents of the Invention."

Many of these uses are directly analogous to a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed

utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating, "[t]he claimed nucleic acid compounds are not supported by a specific asserted utility because the disclosed uses of the nucleic acids (and proteins encoded by said nucleic acids) are not specific and are generally applicable to any nucleic acid and/or protein." Office Action, at page 6, section 10. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moveover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a

broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified be any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

Surprisingly, the Examiner notes that the credibility of the presently asserted utilities has not been asserted. Office Action, at page 7. Credibility is precisely the issue that the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 752 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The

Examiner "must do more than merely question – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Here the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1 and 4-12 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

VI. Rejection of Claims 1 and 4-12, Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at page 8, section 11, the Examiner has rejected claims 1 and 4-12 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Applicants respectfully traverse this rejection. This rejection has been overcome by the foregoing arguments regarding utility. Thus this rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

VII. Rejection of Claims 1 and 4-12 Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at pages 8-10, section 12, the Examiner has rejected claims 1 and 4-12 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Applicants respectfully traverse this rejection.

The Examiner asserts that Applicants have not adequately described the claimed genus of nucleic acid molecules because Applicants allegedly have not provided information regarding the coding regions of the claimed cDNAs and have not adequately described a representative number of claimed nucleic acid molecules. Applicants respectfully disagree with these contentions.

An adequate written description of a genus of nucleic acids, as recited in claims 1 and 4-12, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend

otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (e.g., an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner further contends that the skilled artisan cannot envision the detailed chemical structure of the claimed polynucleotides and/or proteins. According to the Examiner, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of this proposition, the Examiner relies on *Regents of the University of California v. Eli Lilly and Co*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398, (Fed. Cir. 1997). Applicants respectfully disagree. In *Eli Lilly* the court found that claims to a vertebrate cDNA coding insulin were inadequately described. However, the present case is clearly different. Specifically, the present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. *Id.* at 1568-69 ("a cDNA is not defined

or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.").

In particular, Applicants have provided a detailed chemical structure, i.e., the nucleic acid sequence of SEQ ID NOs: 1-5221. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable- they comprise a nucleic acid molecule having the sequence selected from the group consisting of SEQ ID NO: 1 and complements thereof. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claims 1 and 4-12. Thus, claims 1, and 4 through 12 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

VIII. Rejection of Claims 1 and 4-12, Under 35 U.S.C. § 112, Second Paragraph

Rejection of claims 1 and 4-12

In the Office Action, at page 12, section 14, the Examiner has rejected claims 1 and 4-12 under 35 U.S.C. § 112, second paragraph, as being indefinite for being directed to non-elected subject matter. Applicants respectfully submit that this rejection is rendered moot by the foregoing amendment. In light of the amended claims, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection of claim 1

In the Office Action, at page 12, section 14, the Examiner has rejected claim 1

under 35 U.S.C. § 112, second paragraph allegedly being indefinite for using the term "fragment." Applicants respectfully disagree. However, to facilitate prosecution, Applicants have deleted the term "fragment." Reconsideration and withdrawal are respectfully requested.

Rejection of claims 4 and 5

In the Office Action, at page 13, section 14, the Examiner has rejected claims 4 and 5 under 35 U.S.C. § 112, second paragraph as being indefinite for recitation of the phrase "structural" nucleic acid molecule. The Examiner asserts that due to the indefinite nature of the term "structural" the metes and bounds of this term cannot be determined. Applicants respectfully disagree. However, to facilitate prosecution, the Applicants have amended claims 4 and 5 to remove the term "structural." Reconsideration and withdrawal of this rejection are respectfully requested.

Rejection of claim 8

In the Office Action, at pages 13 and 14, section 14, the Examiner has rejected claim 8 under 35 U.S.C. § 112, second paragraph as being indefinite for allegedly lacking antecedent basis for the phrases "said enzyme" and "said plant cell or plant tissue," and for use of the term "predictive." By the foregoing amendments this rejection, as it relates to the phrases "said enzyme" and "said plant cell or plant tissue," has been accommodated. Reconsideration and withdrawal of this portion of the rejection are respectfully requested. Applicants respectfully traverse this rejection as it relates to the use of the term "predictive."

It is well established in the law that an Applicant may define what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art. *See M.P.E.P. § 2173.01*. Further, a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. *In re Swinehart,* 439 F.2d 210, 160 USPQ 226 (CCPA 1971). As such, this portion of the Examiner's rejection is improper. Reconsideration and withdrawal are respectfully requested.

IX. Summary

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

In the Specification at page 7, lines 12-21:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ)([http://]www.ddbj.nig.ac.jp/); Genebank ([http://]www.ncbi.nlm.nih.gov/web/Genbank/Index.[htlm]html); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) ([http://]www.ebi.ac.uk/ebi_docs/embl_db.html). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequences queries (BLASTN, BLASTX, and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology, 12:* 76-80 (1994); Birren, *et al., Genome Analysis, 1:* 543-559 (1997)).

In the claims:

1. A substantially purified nucleic acid molecule [that encodes a soybean protein or fragment thereof] comprising a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1[through SEQ ID NO: 5521].

4. A transformed plant having a nucleic acid molecule which comprises:

(a) an exogenous promoter region which functions in a plant cell to cause the production of a mRNA molecule;

(b) a [structural] nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 [through SEQ ID NO: 5521 or] and complements thereof;

(c) a 3' non-translated sequence that functions in said plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

5. The transformed plant according to claim 4, wherein said structural nucleic acid molecule is a complement of [any of the] a nucleic acid sequence[s of] SEQ ID NO: 1 [through SEQ ID NO: 5521].

8. A method for determining a level or pattern in a plant cell or plant tissue of a protein in a plant comprising:

(a) incubating, under conditions permitting nucleic acid hybridization, a marker nucleic acid molecule, said marker nucleic acid molecule selected from the group of marker nucleic acid molecules which specifically hybridize to a nucleic acid molecule having the nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 [through SEQ ID NO: 5521 or] and complement thereof, with a complementary nucleic acid molecule obtained from said plant cell or plant tissue, wherein nucleic acid hybridization between said marker nucleic acid molecule and said complementary nucleic acid molecule obtained from said plant cell or plant tissue permits the detection of an mRNA for said protein [enzyme];

(b) permitting hybridization between said marker nucleic acid molecule and said complementary nucleic acid molecule obtained from said plant cell or plant tissue; and

(c) detecting the level or pattern of said complementary nucleic acid, wherein the detection of said complementary nucleic acid is predictive of the level or pattern of said protein.